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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE SCHERING-PLOUGH CORPORATION SHAREHOLDERS DERIVATIVE LITIGATION	Master Derivative Docket No. 01-1412 (NHP)
THIS DOCUMENT RELATES TO ALL ACTIONS	

JOINT AND CONSOLIDATED SECOND AMENDED SHAREHOLDER DERIVATIVE COMPLAINT

Plaintiffs, by and through their undersigned counsel, and based on personal knowledge as to themselves and their own acts and on information and belief as to all other matters based upon an investigation by plaintiffs' counsel, allege for their Joint and Consolidated Second Amended Shareholder Derivative Complaint (the "Second Amended Complaint") as follows:

INTRODUCTION

1. This is a shareholder derivative action brought on behalf of Schering-Plough Corporation ("Schering" or the "Company") to recover for damages caused to the Company by the Defendants' breaches of fiduciary duty owed to the Company and its shareholders.

2. As detailed herein, Defendants intentionally or recklessly ignored repeated, clear, and unmistakable warnings that essential Company production facilities -- responsible for the manufacture of virtually every significant prescription and over-the -counter drug Schering sells -- were plagued by severe and pervasive manufacturing and quality control system breakdowns and failures which threatened not only the Company's good standing with federal regulatory authorities, but also its ability to successfully manufacture and market its most important products. Further, Defendants intentionally or recklessly authorized and/or permitted the Company to engage in improper sales practices which operated as a fraud upon federal and state governmental authorities, thereby exposing the Company to a series of ongoing federal and state investigations and jeopardizing its all-important eligibility to participate in Medicaid and other government programs.

3. As the direct result of Defendants' intentional or reckless misconduct, Schering has been severely damaged.

JURISDICTION AND VENUE

4. This derivative action is brought pursuant to Rule 23.1 of the Federal Rules of Civil Procedure.

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1332 and 1367. The amount in controversy exceeds $75,000, exclusive of interest and costs.

6. This action is not brought collusively to confer jurisdiction on this Court which it would not otherwise have. Schering is headquartered within this District, and the Company and the Defendants are subject to personal jurisdiction in this District. Venue is proper in this District because some or all of the events, actions, and failures to act giving rise to the claims asserted herein occurred in this District.

THE PARTIES

THE DEMAND FUTILITY PLAINTIFFS

7. Plaintiff Richard Pendolphia brought this action on behalf of Laborers Tri-County Pension Fund ("the Fund"). The Fund is a citizen of the Commonwealth of Pennsylvania. The Fund, at all times relevant to this action up to October 2006, was the owner of shares of the common stock of Schering.

8. Plaintiff Helene Gissen Revocable Trust a/k/a Helene Rosenthal (the "Trust") is a citizen of Florida. The Trust, at all times relevant to this action up to December 2004, was the owner of shares of the common stock of Schering.

9. Philip E. McCarthy ("McCarthy"), a citizen of Florida, at all times relevant to this action is and has been the owner of shares of the common stock of Schering.

10. Plaintiff William W. Prager, Jr. ("Prager"), a citizen of New York, at all times relevant to this action is and has been the owner of shares of common stock of Schering.

11. McCarthy, Prager, the Fund and the Trust, allege that, as set forth herein, demand on the board of directors of Schering (the "Board") would be futile and therefore excused.

THE DEMAND MADE PLAINTIFF

12. Plaintiff David Scherr ("Scherr"), a resident of New York, at all times relevant to this action is and has been the owner of shares of common stock of Schering.

13. As detailed herein Scherr made a demand on the Board and alleges that his demand was wrongfully refused.

DEFENDANTS

A. Officer Directors

14. Defendant Richard J. Kogan ("Kogan") is and has been the Chairman of Schering's Board of Directors and Schering's Chief Executive Officer since November 1998. Before that time, from January 1996 to November 1998, Kogan was the President and Chief Executive Officer of the Company. He is also a director of Colgate-Palmolive Company and The Bank of New York Company, Inc. Sitting with him as directors of Bank of New York are defendants Miller and Morley. Prior to joining Schering, Kogan was employed by Ciba-Geigy Corporation along with defendants D'Andrade and Luciano. For the 2000 calendar year, Kogan received a salary of $1,338,000 and a bonus of $1,872,000. In light of the impact in the corporation of the manufacturing deficiencies, Kogan's bonus was reduced by $300,000 based upon the recommendation of the Executive Compensation and Organization Committee of the Schering Board.

15. Defendant Raul Cesan ("Cesan") was the President, Chief Operating Officer and a director of Schering from November 1998 until his resignation on July 15, 2001. From September 1994 through November 1998, defendant Cesan was Schering's Executive Vice President - Pharmaceuticals. He is also a director of The New York Times Corporation, and a member of the Healthcare Leadership Council and the Healthcare Institute of New Jersey. For the 2000 calendar year, Cesan received no bonus in light of the impact on the corporation of the manufacturing deficiencies based upon the recommendation of the Executive Compensation and Organization Committee of the Schering Board but still received a salary of $918,000.

16. Defendant Hugh A. D'Andrade ("D'Andrade") was the Vice Chairman and Chief Administrative Officer of Schering from January 1996 to at least October 2000. D'Andrade was the

Company's Executive Vice President - Administration from January 1985 to December 1995. Defendant D'Andrade retired from Schering as of December 31, 2000, and is no longer a member of Schering's Board of Directors. D'Andrade is currently chairman of the board of directors of Myriad Genetics Inc., which has established strategic alliances with Schering.

B. Finance, Compliance and Audit Review Committee Directors

17. Defendant Hans W. Becherer ("Becherer") is and has been a member of Schering's Board of Directors since 1989. During that time, defendant Becherer has been a member of the Finance, Compliance and Audit Review Committee, the Nominating Committee and the Executive Compensation and Organization Committee of Schering's Board of Directors. He is also a member of the board of directors of Honeywell, Inc. and J.P. Morgan Chase & Co. Sitting with him as a director at Honeywell is defendant Luciano.

18. Defendant H. Barclay Morley ("Morley") is and has been a member of Schering's Board of Directors since 1979. Since 1987, defendant Morley has been a member of the Finance, Compliance and Audit Review Committee, the Nominating Committee and the Executive Compensation and Organization Committee of Schering's Board of Directors. Since 1997, he has also been a member of the board of directors of The Bank of New York Company, Inc. He is also the former chairman and chief executive officer of Stauffer Chemical Company.

19. Defendant Richard J. Osborne ("Osborne") is and has been a member of Schering's Board of Directors since 1988. During that time, defendant Osborne has been a member of, and at least since 2000 has headed the Finance, Compliance and Audit Review Committee, the Nominating Committee and the Executive Compensation and Organization Committee of Schering's Board of Directors. He is also the non-executive chairman and a director of Datawatch Corporation with

defendants van Oordt and Wood, and serves as a director of BFGoodrich Company, Birmingham Steel Corporation, NACCO Industries, Inc., and The Tinker Foundation.

20. Defendant Robert F. van Oordt ("van Oordt") is and has been a member of Schering's Board of Directors since 1992. During that time, defendant van Oordt has been a member of the Finance, Compliance and Audit Review Committee and the Nominating Committee of Schering's Board of Directors. He is also chairman of the board and chief executive officer of Rodamco Continental Europe N.V, and as a director of Datawatch Corporation.

21. Defendant Arthur F. Weinbach ("Weinbach") is and has been a member of Schering's Board of Directors since 1999. During that time, defendant Weinbach has been a member of the Finance, Compliance and Audit Review Committee of Schering's Board of Directors. He is also chairman of the board and chief executive officer of Automatic Data Processing, Inc., and serves as a director of First Data Corp.

22. Defendant Regina E. Herzlinger ("Herzlinger") is and has been a director of Schering since 1992. During that time, defendant Herzlinger has been a member of the Finance, Compliance and Audit Review Committee of Schering's Board of Directors. She is also a director of Cardinal Health, Inc., C.R. Bard, Inc., Nanogen, Inc., Deere & Company, and Novan Pharmaceuticals Inc.

23. The Finance, Audit and Compliance Committee is responsible for monitoring: (1) the Company's financial reporting process; (2) the independence and performance of the Company's independent auditors and internal auditing department; and (3) compliance by the company with legal and regulatory requirements. The Committee's activities include meeting periodically with management, the internal auditors and the independent auditors to discuss their

independence and to review audit results, financial reporting, internal controls and other financial matters.

C. Other Director Defendants

24. Defendant David H. Komansky ("Komansky") is and has been a director of Schering since October 25, 2000. Since 1997, he had been chairman and chief executive officer of Merrill Lynch & Co., Inc. During 2000 and continuing to the present, Merrill Lynch & Co., Inc. has provided to Schering investment banking, financial advisory, and other services.

25. Defendant Robert P. Luciano ("Luciano") was a director of Schering from 1978 until his retirement on October 18, 2001. Luciano was Schering's chief executive officer from 1982 through 1995. He also serves as a director of C.R. Bard, Inc., Honeywell, Inc. with defendant Becherer, and Merrill Lynch & Co., Inc. with defendant Komansky.

26. Defendant Eugene R. McGrath ("McGrath") is and has been a director of Schering since 2000. McGrath has been associated with Consolidated Edison Inc. since 1963, where, since 1997, he has served as chairman of the board, president and chief executive officer.

27. Defendant Donald L. Miller ("Miller") is and has been a director of Schering since 1997. He is a member of the Nominating Committee of the Board of Directors. He also served as a director of The Bank of New York Company, Inc. and Community Banks Inc.

28. Defendant Carl E. Mundy ("Mundy") is and has been a director of Schering since 1995. He is a member of the Nominating Committee of the Board of Directors. Since 1999, he has also served as a director of General Dynamics Corporation.

29. Defendant Patricia F. Russo ("Russo) is and has been a director of Schering since 1995. She is a member of the Nominating Committee and the Executive Compensation and

Organization Committee of the Board of Directors. She has also served as a director of Xerox Corporation and Avaya, and is currently the chief operating officer and president of Eastman Kodak Co.

30. Defendant James Wood ("Wood") is and has been a director of Schering since 1987. He is a member of the Executive Compensation and Organization Committee of the Board of Directors. He is currently the chairman and board of director of Great Atlantic & Pacific Tea Company, Inc. He has also served as a director of Datawatch Corporation.

31. Defendants Becherer, Cesan, D'Andrade, Herzlinger, Kogan, Luciano, McGrath, Miller, Morley, Mundy, Osborne, Komansky, Russo, van Oordt, Weinbach and Wood are collectively referred to herein as "Defendants." As of the date this action was originally commenced, none of the Defendants was a citizen of the State of Florida, and none of the Defendants was a citizen of the Commonwealth of Pennsylvania.

NOMINAL DEFENDANT

32. Nominal defendant Schering is a New Jersey corporation with its headquarters located in Madison, New Jersey. Schering is a holding company for subsidiaries engaged in the discovery, development, manufacturing, and marketing of both prescription and over-the-counter pharmaceutical products throughout the world. Among the Company's most noted products are prescription allergy medicines, Claritin and Nasonex, and asthma-related aerosol inhalers. Schering has three basic product lines: Prescription - allergy/respiratory, anti-infective and anti-cancer; Dermatologicals; and Cardiovasculars.

DEFENDANTS' DUTIES TO SCHERING AND ITS SHAREHOLDERS

33. Because of their membership on the Board, the Finance, Compliance and Audit Review Committee of the Board, and/or senior executive and managerial positions, Defendants, pursuant to New Jersey law, owed the Company and its stockholders fiduciary obligations of candor, fidelity, trust, and loyalty, and are and were required to use their ability to control and direct Schering in a fair, just, and equitable manner, as well as to act in furtherance of the best interests of Schering and its stockholders. In addition, while they occupied their directorships, Defendants owed Schering the fiduciary duty to exercise due care and diligence in the management and administration of the affairs of the Company, and in the use and preservation of its property and assets.

34. To discharge the aforesaid duties under New Jersey law, Defendants were required to exercise reasonable and prudent supervision over management and the policies, practices, controls, and financial affairs of the Company pursuant to their fiduciary obligations to use the same care and diligence as would an ordinary prudent person in a like position. Specifically, Defendants were required, among other things:

(i) to, in good faith, manage, conduct, supervise, and direct the business and affairs of Schering carefully and prudently, and in accordance with the laws of New Jersey, the laws of the United States, and the Company's own charter and by-laws;

(ii) to neither violate nor intentionally or recklessly permit any officer, director, or employee of Schering to violate applicable federal and state laws, rules and regulations, or any Company rule or regulation;

(iii) to ensure Schering has in place reasonable and effective systems and controls regarding critical business functions, including safe and compliant drug manufacture and production quality control;

(iv) to remain informed as to the status of Schering's operations, and, upon receipt of notice or information of imprudent, illegal, or unsound practices, to make a reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices, and make such disclosures as are necessary to comply with federal and state laws;

(v) to exercise reasonable control and supervision over the Company's public statements to the securities markets by Schering's officers and employees;

(vi) to supervise the preparation, filing, and/or dissemination of any Securities and Exchange Commission ("SEC") filings, press releases, audits, reports, or other information required by law, to examine and evaluate any audits or other financial information concerning the financial condition of Schering, and to cause Schering to obey and comply with and not violate the federal or state securities laws; and

(vii) to maintain and implement an adequate system of controls and information systems, such that no officer, director, or employee of the Company would make false statements about Schering to the securities markets or would be able to or encouraged to violate federal or state laws restricting insider trading.

35. Defendants Becherer, Morley, Herzlinger, Osborne, van Oordt, and Weinbach, as members of the Company's Finance, Compliance and Audit Review Committee, had access to internal corporate documents (including Schering's operating plans, forecasts, and reports of actual operation), and had conversations and connections with corporate officers and employees,

including internal auditing and financial managers, and received reports and other information in connection with their duties as Finance, Compliance and Audit Review Committee members.

36. Because of their membership on the Board, membership on the Finance, Compliance and Audit Review Committee of the Board and/or senior most executive and managerial positions with Schering, each of the Defendants had access to adverse non-public information about Schering's financial performance and condition, including the following facts: (i) Schering's receipt of multiple adverse reports of inspection and four separate Warning Letters from the Food and Drug Administration ("FDA") regarding principal manufacturing facilities; (ii) the Company's consistent failure to comply with current Good Manufacturing Practices ("GMPs") and other FDA regulatory drug manufacturing standards; and (iii) Defendants' long-standing failure to commit sufficient oversight, control, and resources to redress and correct the material and pervasive deficiencies in Schering's manufacturing facilities, processes, and practices.

37. In violation of their fiduciary duties, Defendants permitted and/or caused Schering to conduct its business in an unsafe, imprudent, illegal, and/or dangerous manner by: (i) failing to timely or adequately institute and implement fundamental systems to oversee and monitor quality control and basic manufacturing processes and practices; (ii) failing to take reasonable efforts to correct deficiencies in the quality control and regulatory compliance functions of Schering's manufacturing facilities once they were repeatedly and unambiguously brought to their attention; (iii) failing to fully and/or accurately report the Company's true financial condition; and (iv) using non-public corporate information for their own personal benefit and financial gain. Defendants' conduct, as detailed more fully herein, involves a knowing, culpable, and/or reckless

violation of their obligations as directors of Schering, an absence of good faith on their part, and a blatant disregard for their duties to the Company and its shareholders which the Directors knew or recklessly disregarded created a substantial risk of economic and reputational injury to the Company.

38. Indeed, the Form 10-K for the year ended December 31, 2000, signed by defendants Kogan, Cesan, Becherer, Herzlinger, Luciano, McGrath, Osborne, Russo, van Oordt, Weinbach and Wood stated that "failure to comply with government regulations can result in delays in the release of products, delays in the approvals of new products, seizure or recall of products, suspension or revocation of the authority necessary for the production and sale of products, fines, and other civil or criminal sanctions."

FACTUAL BACKGROUND

39. Defendants, as members of Schering's Board of Directors, acted in violation of their fiduciary duties by intentionally or recklessly ignoring repeated clear and unambiguous warnings and red flags that the Company's production and manufacturing facilities were plagued by severe and systemic problems. Specifically, Defendants failed to insure that Schering maintained basic quality and management policies and procedures. As a result, Schering's principal manufacturing facilities, including those in Kenilworth and Union, New Jersey and those in Manati and Las Piedras, Puerto Rico, have been the subject of repeated, specific adverse findings by the FDA. Indeed, the nature and scope of the pervasive manufacturing and quality control problems long plaguing the Company are so serious and substantial as to require the recall of millions of its products and to derail the regulatory approval process of the Company's

single most important new drug, all at significant cost and injury to the Company and its reputation.

40. As detailed more fully herein, Defendants cannot make any credible claim of lack of knowledge of the true extent and severe nature of these quality control and manufacturing deficiencies as the FDA has undertaken multiple inspections and issued a barrage of highly negative inspection reports and even multiple Warning Letters in the past three years, setting forth in detail the Company's consistent failure to ensure even basic compliance with GMP and Finished Pharmaceuticals regulations. The deficiencies cited by the FDA and other professionals -- both in-house and paid outside consultants -- engaged to inspect Schering's manufacturing processes were so fundamental and pervasive, affecting the Company's biggest selling and most profitable products, and thus putting at risk the Company's present and future profitability, that they could not -- and did not -- go unnoticed by Defendants.

41. In the face of these clear, repeated, and unambiguous red flags, Defendants consistently failed to take any effective or reasonable action. Instead of providing sufficient resources, direction, and oversight to ensure the implementation and enforcement of even the most basic and fundamental quality control, compliance and manufacturing guidelines, Defendants instead fostered and maintained a corporate environment where employees were encouraged to actively ignore quality control protections and to deviate from, or were provided insufficient resources to comply with, statutorily imposed GMP and Finished Pharmaceuticals regulations. As a result, Schering has been harmed by reason of, for example, the costs and serious damage to Schering's reputation resulting from Schering's recalls of its products,[1] its

1 In Schering's Form 10-K for the year ended December 31, 2000, signed by defendants, it was disclosed that "sales

ultimate public disclosure of the true extent and pervasive scope of its manufacturing problems, and its announcement on February 15, 2001, that the FDA was withholding approval of Clarinex™ (desloratadine), Schering's next purported "wonder" drug, until outstanding GMP deficiencies were resolved. In addition, Schering is the subject of securities fraud class actions because Defendants allegedly issued false and misleading public representations regarding the true financial condition of the Company.

Regulatory Framework for FDA Oversight:

42. The FDA is the federal agency with principal oversight responsibility over pharmaceutical companies in the United States, with the power to, inter alia, shut down production and impose product recalls. Schering was and is required at all times to meet the standards for current GMP established by the FDA. Current GMP statutory standards, codified at 21 C.F.R. §§210, 211, set forth:

> the minimum current good manufacturing practices for methods to be used in, and the facilities and controls to be used for the manufacture, processing, packing or holding of a drug to assure that such drug meets the requirements of the [Federal Food, Drug and Cosmetic Act] as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

43. Pharmaceutical products manufactured in violation of GMPs are deemed to be "adulterated" within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.

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of Vanceril, an orally inhale steroid for asthma declined $52 million in 2000 and $14 million in 1999 due primarily to manufacturing issues. U.S. sales of the proventil (albuterol) line of asthma products declined $54 million in 2000 due to manufacturing issues and continued generic competition.

§351(a)(2)(B), and any firm responsible for the manufacture of adulterated product "shall be subject to regulatory action." 21 C.F.R. §210.1(b).

44. GMP regulations require drug manufacturers to develop and follow detailed written procedures for all aspects of the production, testing, storage, labeling, and distribution of drug products. Moreover, the FDA's GMP regulations also provide for the establishment of a quality control unit within each drug manufacturer whose responsibilities include approving or rejecting "all components, drug product containers, closures, in-process material, labeling, and drug products," and the review of "production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated." §211.22(a).

45. As part of their oversight function, the FDA undertakes periodic inspections of drug manufacturing facilities to monitor compliance with GMP and Finished Pharmaceuticals regulations. Results of such inspections are provided to the manufacturer in the form of FDA 483 reports of inspectional observation and, in severe circumstances, the issuance of a Warning Letter. FDA 483 reports, typically provided to management upon completion of an FDA inspection, are used to notify management of significant conditions or problems relating to products and/or processes uncovered during the inspection. The FDA issues Warning Letters to drug manufacturers only when observed problems or violations are of "regulatory significance," i.e., when their failure to be adequately and promptly corrected could be expected to result in enforcement action taken against the manufacturer.

46. For these reasons, receipt of multiple adverse FDA 483 reports of inspection and even Warning Letters detailing significant deficiencies in quality control and manufacturing processes and practices at critical manufacturing facilities would be a highly material event about

which any reasonably active and diligent Board would be fully informed and actively involved with.

Defendants Received Repeated Warning Letters from the FDA of the Pervasive Problems at Key Manufacturing Facilities:

47. At a minimum, as detailed herein, over the past three years the FDA has undertaken multiple inspections of principal manufacturing operations and facilities at Schering.

48. For example, between March 18 and May 7, 1998, the FDA undertook an inspection of Schering's manufacturing facility at Las Piedras, Puerto Rico. Both the results of this inspection and Schering's failure to adequately respond were so material that, in late June of 1998, the FDA took the significant step of issuing a Warning Letter to the Las Piedras General Manager. The Warning Letter, which was not publicly disclosed by Schering at the time, advised Schering that upon its inspection, the FDA had documented deviations from FDA GMP regulations and New Drug Application Field Alert Regulations which caused the Company's Theo-Dur Extended Release Tablets to be classified by the FDA as "adulterated," and cautioned that the pending New Drug Applications "may not be approved" until the violations were corrected.

49. Among the violations documented in the June 1998 Warning Letter were: (i) the failure to account for manufacturing holding periods of up to 18 months in ascribing expiration dates for drug packages; (ii) the failure to conduct in-process testing of all lots of intermediate materials used in the manufacturing process; and (iii) the failure to timely submit Field Alert Reports advising of the failure of specific lots of drugs to satisfy quality testing. In the warning letter, the FDA warned: "...pending NDA, ANDA or expert approval requests may not be approved until the above violations are corrected."

50. Significantly, the June 1998 Warning Letter raised FDA concerns about Schering's single biggest selling drug -- Claritin -- responsible for over $3 billion (or approximately 30% of the Company's entire worldwide sales) for 2000. This Warning Letter noted problems with "the variability in absorbance during testing," and directed the Company to "conduct a full investigation to assess the cause of the problem."

51. In light of the extent of the problems uncovered, and the fact they affected Claritin, the Company's number one selling drug worldwide, the Defendants knew or were reckless in not knowing of both the underlying FDA inspections at the Las Piedras manufacturing facility, and the Company's receipt of the June 1998 FDA Warning Letter highlighting the deficiencies uncovered there.

52. Schering, in its public filings, lists its Kenilworth and Union, New Jersey operations as the first among the Company's "principal" manufacturing and research facilities. The FDA undertook an inspection of these critical facilities between June 29 and July 30, 1998. Again, based on the seriousness of the adverse findings uncovered and the Company's failure to adequately address these problems, on October 23, 1998, the FDA sent Schering its second Warning Letter in less than four months, this one directed to the President, Technical Operations of Schering.

53. The October 1998 Warning Letter advised Schering that its manufacturing facilities in Union and Kenilworth had also been found upon inspection to deviate significantly from GMPs and Finished Pharmaceutical regulations. The FDA further found that these deviations caused Schering's finished pharmaceuticals from these plants to be "adulterated" within the meaning of the Federal Food, Drug and Cosmetic Act.

54. The Defendants knew or recklessly disregarded the potential adverse financial consequences to Schering of the FDA's inspection findings as they included, inter alia, uncovering additional serious problems with the manufacture of Claritin, as well with Diprolene Ointment, Nasonex Nasal Spray (a major allergy/respiratory product responsible for generating $415 million in sales in 2000), and Proventil Inhaler (a second key allergy/respiratory product generating almost $200 million in sales in 2000).

55. Specifically, the problems cited by the FDA in the New Jersey plants included: (i) the lack of assurance that written production and process control procedures for coating Claritin-D 12 hour Repetabs were sufficient to produce a product that has the quality it is represented to possess, finding specifically that the Company had released to the public portions of batches of Claritin even after quality-control tests showed that some of the product thus released dissolved more quickly than it should have, a problem which had already required the rejection of 78 batches of Claritin manufactured in 1997, and 79 batches manufactured in 1998; (ii) the fact pan operators were using visual determinations of coating cycles rather than any written guideline for assessing whether coating solutions were evenly distributed; and (iii) the fact the Company had made partial release to the public of various products despite having out-of-specification test results, even though no data existed to invalidate these adverse results. Products released in the face of clear out-of-specification test results included Diprolene anti-inflammation ointment in the wrong concentrations, Proventil inhalers with the wrong pressure, and Nasonex nasal spray that failed to spray properly.

56. In recognition of the obvious seriousness of the FDA's adverse findings at the critical Kenilworth and Union facilities and their potential negative financial consequences to

Schering, in August or September 1998 -- after the inspection but even prior to receipt of the October 1998 FDA Warning Letter -- Schering created an in-house task force of representatives from its Research, Quality Control, and Manufacturing Operations to further evaluate the critical manufacturing parameters of Claritin-D12 Hour Repetabs and Proventil Repetabs.

57. Based, inter alia, on the nature and scope of these adverse FDA findings -- triggering a second Warning Letter in less than four months, directly affecting two of the Company's principal manufacturing facilities, and raising significant manufacturing concerns about its single most profitable drug, Claritin -- the Directors knew or were reckless in not knowing about the FDA inspection at Kenilworth, the creation of the in-house task force, and the subsequent receipt of the second FDA Warning Letter. Thus, the Directors knew or recklessly disregarded that the FDA observed in its October 1998 Warning Letter that while the task force appeared to be addressing the issues related to release criteria, it still did not resolve the reasons for in-process dissolution failures. In addition, the FDA noted that as of October 1998, the FDA had still not received a timetable from the task force as to when its evaluation would be completed. In addition, in that same letter, Schering was warned that "failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction."

58. With respect to Schering's practice of "partial" releases -- e.g., releasing part of a production run for a drug despite having found defects in the run -- the FDA's October 1998 Warning Letter concluded:

> Released products are expected to conform to established specifications from the beginning to the end of production. Current regulations specify that drug products failing to meet established standards or specifications and any other relevant quality control

> criteria shall be rejected. Reprocessing may be performed, provided certain criteria are met according to written procedures. The practice of partial releases, no matter how stringent the re-sampling, raises doubts as to the safety and efficacy of the product being released. It is not acceptable to substitute testing over adequate control of process.

59. Between April 12 and May 28, 1999, the FDA undertook another inspection of Schering's critical Kenilworth and Union facilities. The FDA issued a FDA 483 report to the Company on May 28, 1999 which listed twelve observations of GMPs violations affecting, inter alia, Proventil Inhaler Aerosol, as well as Vanceril DS (Double Strength)Aerosol Inhalers and Vancenase Pockethaler (two allergy/respiratory products generating of $127 million and $175 million, respectively, in 2000).

60. Based upon Schering's inability to timely or adequately respond to the concerns raised in the May 28, 1999 FDA 483 report, on July 21, 1999 -- only eight months after issuing the October 1998 Warning Letter -- the FDA issued a second Warning Letter regarding violations of GMPs and Finished Pharmaceuticals regulations at the Kenilworth and Union facilities, again finding finished pharmaceuticals manufactured there to be "adulterated" within the meaning of the Federal Food, Drug and Cosmetic Act.

61. Among the particular deviations cited by the FDA were: (i) the failure to reject batches of Vanceril DS Inhalation Aerosol that did not meet established test specifications; (ii) the failure to follow written test procedures in nine batches of Vanceril DS Inhalers resulting in release of batches that did not satisfy written test procedures; and (iii) the failure to subject Proventil (albuterol) Inhalation Aerosol to testing as required.

62. The adverse findings of this FDA inspection and the subsequent Warning Letter forced Schering to cease distribution of Proventil Inhalation Aerosol. Schering representatives,

including Dr. Alexander Giaquinto, the Senior Vice President, Worldwide Regulatory Affairs, met with members of the FDA to negotiate the conditions under which Schering could continue distribution, including a requirement that Schering submit to the FDA as a "Prior Approval" supplement, the results of a new four phase proposal of the "interim steps" Schering was required to take "in order to continue distribution of this product." Recognizing the pervasive and continuing nature of the problems observed, the FDA stated in its July 1999 Warning Letter: "As we pointed out in our previous Warning Letter of October 23, 1998, drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Retesting later is not an acceptable practice." Once again, the FDA warned Schering "failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction."

63. Following these inspections and the highly critical adverse FDA findings resulting therefrom, in late 1999 the Company undertook two product recalls. The first, announced on September 9, 1999, entailed the recall of a single lot -- involving approximately 190,000 units -- of albuterol metered dose inhaler aerosol (Schering's "generic" version of Proventil Aerosol Inhaler). The second recall, announced on December 2, 1999, entailed five lots -- involving more than 80,000 units -- of Vanceril DS Inhalation Aerosol. Both of these recalls were triggered by the "discovery" that some of the aerosol canisters may not have contained any active ingredient.

64. Between December 9, 1999 and February 25, 2000, the FDA undertook yet another inspection of Kenilworth and Union, New Jersey manufacturing facilities, resulting in another adverse FDA 483 report being issued to Schering. This inspection report detailed

eighteen separate violations, many with multiple sub-parts. These material adverse findings, manifesting substantial and pervasive problems still present more than one and one-half years after the FDA's 1998 inspection, manifested senior management's continued and unacceptable abdication of responsibility and oversight.

65. For example, despite repeated prior FDA adverse findings regarding Schering's aerosol inhaler production, and despite the two recently completed aerosol product recalls, the February 25, 2000 FDA 483 report specifically found:

> There is no assurance that canisters with no active ingredient, drug concentrate only, propellant only or empty canisters, will not be found in batches of Proventil (Albuterol), Vanceril, Vanceril Double Strength and Vancenase Pocket Inhalation Aerosols manufactured prior to 11/22/99.

66. As the result of the highly critical February 25, 2000 FDA 483 report and further communications between the Company and the FDA, on March 8, 2000 Schering announced a third recall of inhalation aerosols manufactured before September 30, 1999. This recall included nearly 59 million units of Proventil, almost 6 million units of Vanceril, and more than 2.7 million units of Vancenase. Like the prior recalls, this massive recall was triggered because the Company could not provide adequate assurance of the fundamental fact that all canisters distributed to the consuming public actually contained active ingredient.

67. Between November 30, 1999 and March 28, 2000, the FDA conducted an inspection of Schering's Manati, Puerto Rico manufacturing facility. As with prior inspections,

the FDA again uncovered substantial GMP violations affecting multiple products, and issued the Company a FDA 483 report on March 28, 2000.

68. Based in part on the serious nature of the violations highlighted on the March 28, 2000 FDA 483 report and the Company's inadequate response thereto, on May 8, 2000, the FDA issued its fourth Warning Letter to Schering in less than 24 months, this time arising from its recent inspection at Manati, Puerto Rico. This Warning Letter, like its three predecessors, again raised substantial concerns regarding the quality control and drug manufacturing processes and practices in place at the Company. The May 2000 Warning Letter advised Schering that the pharmaceutical products manufactured at the Manati plant were "adulterated" within the meaning of the Federal Food, Drug and Cosmetic Act because of Schering's continuing failure to follow GMPs. The adverse findings of the May 2000 Warning Letter included: (i) the failure to perform adequate investigation into the cause of out-of-specification results for stability testing of Gentocin Opthalmic Solution; (ii) inadequate laboratory controls, including failures to document Method Validation for the stability assay method for Trilafon Injection, to document changes to written specifications, and to have the changes approved before implementation; (iii) the failure to maintain complete data from all laboratory tests; (iv) the failure to follow written procedures for cleaning equipment; (v) the failure to test drug product components to assure they meet current specifications; and (vi) the failure to use reliable, meaningful, and specific test methods for stability testing of drug products. In this letter, the FDA again warned Schering of the possibility of regulatory action without further notice, including seizure and/or injunction.

69. As detailed above, Defendants knew or were reckless in failing to know of: (i) each of the FDA inspections at the New Jersey and Puerto Rico manufacturing facilities; (ii) the

seriously adverse results and findings of these inspections; and (iii) the receipt and content of each FDA Warning Letter issued in connection therewith.

70. While Schering consistently publicly ignored or downplayed and minimized the significance and effect of FDA Warning Letters, the pervasive problems triggering them had a clear and material impact on both the Company and the Defendants. For example, these material adverse FDA findings dictated, or at least substantially contributed to the multiple product recalls in late 1999 and early 2000 described above. These recalls cost Schering millions of dollars, and damaged the Company's public image as a manufacturer of high quality and effective drugs.

71. In addition, in the face of the stark failure of its own in-house task force in the fall of 1998 and the continuing barrage of negative findings by the FDA, in early 2000, Schering took the significant step of actually hiring an outside consultant, AAC Consulting Group of Rockville, Maryland, to undertake a confidential inspection and audit of its critical Kenilworth manufacturing facility. AAC provides a full range of support and compliance assistance to industries regulated by the FDA. AAC offers validation and compliance programs, and courses designed to train and educate personnel of the intent and application of the FDA GMPS.

The AAC Inspection And Report On Kenilworth

72. Defendants either knew of the retention of AAC or were reckless in failing to know of it because of, inter alia, (i) the serious and repeated nature of the FDA's adverse findings at Kenilworth, one of the Company's principal manufacturing and research facilities; (ii) the fact these adverse findings had a direct and potentially devastating impact on the manufacture and sales of many of the Company's principal product lines, including Claritin and aerosol inhalers; (iii) the fact these adverse findings had already triggered massive product recalls; (iv) the fact the

Company's own in-house task force had proven totally ineffective in resolving these problems; and (v) the fact the Company was actively seeking FDA for approval of a new drug, Clarinex -- critical to the Company's future financial success as the designated heir to Claritin when that drug's patent expired in mid-2002 -- making satisfying the FDA and resolving its prior adverse findings a key imperative for Defendants and senior management.

73. After inspecting the Kenilworth facility from February 28, 2000 through April 14, 2000, AAC issued an over 100 page confidential report dated April 27, 2000. This report documented the fundamental mismanagement of the Company, finding, inter alia, that important aspects of the Company's manufacturing process were "out of control," with the process validation documentation for all product lines found to be "inadequate," and with "quality control/assurance activities" constituting a "major vulnerability." The President of AAC, Anthony Celeste, sent a cover letter to John E. Nine, Schering's Corporate Vice President and President of Technical Operations, accompanying the AAC report. Celeste bluntly stated what the Defendants already knew or recklessly disregarded for years: "The results of the audit revealed a number of serious cGMP systems failures and compliance lapses. It is our view that the facilities and corporation are at serious risk of a significant FDA regulatory action."

74. In his cover letter, AAC's Celeste specifically listed six "basic cGMP areas where there are substantial non-compliance issues and out of control situations," including: (i) validation of processes, support systems and cleaning operations; (ii) out of control HVAC system in tablet granulation and compression areas, creating serious cross-contamination possibilities; (iii) quality control/quality assurance activities; and (iv) quality culture, performance management, and training documentation. Celeste then stated: "The above areas are

viewed as the 'systems' which are 'broken' that are the cause for many of the deviations discovered during the audit."

75. In summation, Celeste stated:

> It is our recommendation that this report be utilized to prepare additional action items that will be incorporated into the overall cGMP Action Plan. These items should be given very high priority for completion. We are concerned that the amount of work required to correct all of the deficiencies to assure substantial cGMP compliance is extensive.

76. The AAC report found that in general Schering's management displayed an attitude with "an imbalance between quality and production, leaning considerably toward production." The pervasive problems with one of the Company's major money-making products – aerosols – were "indicative of insufficient technical expertise and managerial oversight." Indeed, the AAC report observed that:

> this production area does not have the visibility and importance from an organizational standpoint that it needs in order to quickly and effectively recover from past problems, maintain satisfactory regulatory compliance, attract and retain necessary expertise, and grow in the future.

77. AAC further found that the absence of sufficient management oversight led to such gross deficiencies as the failure to even perform an in-process assay for the active ingredient in Proventil. AAC recommended that:

> upper management needs to demonstrate its long term commitment to product quality, such as through increased staffing/budget resource allocations and investments in new equipment, in order to supplant

> the traditional emphasis on production and firmly establish a company culture in which quality is, in fact, the number one priority.

78. Indicative of the absence of upper management's commitment to quality was the AAC's finding of unsanitary conditions in the Albuterol production area of the Kenilworth facility. Specifically, AAC found,

> Backup of sewage in the corridor adjacent to the room where albuterol solution for inhalation is manufactured has been occurring periodically over the last year or two without a plan for permanent correction and without any documentation of the problem or evaluation of product impact. During the early part of the audit, large pools of sewage were observed to form which were then tracked through the production facility. Ingredient containers and hoses came in contact with the floor and fecal organisms were observed to have a pathway to the product. Drugs produced in this area were not evaluated for exposure to fecal contamination.

79. The AAC report further observed that the rapid turnover of personnel had engendered poor employee morale, due to the "the ever-changing personalities and ways of doing business." As a result, the report concluded, the "facilities and corporation are at serious risk of a significant FDA regulatory action."

80. As detailed above, the Directors either knew or were reckless in failing to know of both the retention of AAC and the receipt and content of its confidential inspection report. Yet no effective action was taken to cure these pervasive problems, as evidenced by the continued adverse FDA findings from additional inspections of the New Jersey and Puerto Rico manufacturing facilities undertaken from late 2000 through mid-2001.

Additional FDA Inspections Revealed Defendant's Continued Failure To Take Effective Action To Cure The Company's Long-term And Pervasive Manufacturing And Quality Control Problems:

81. In the period of November 2000 through June 2001, the FDA performed at least seven additional inspections of the Kenilworth and Puerto Rico manufacturing facilities. The FDA's findings from these inspections, provided to the Company in the form of FDA 483 reports, were uniformly adverse, continuing to highlight many of the same pervasive manufacturing and quality control problems long plaguing the Company at these key facilities.

82. The FDA inspected the Manati facility between November 9 and December 14, 2000. The December 14, 2000 FDA 483 report highlighted significant production problems with multiple products. Representative of the Company's dangerous disregard for quality control and safe manufacturing practices, the FDA found, for example, that since February 1999 -- e.g., for almost two years and in the face of a barrage of other FDA warnings about quality control and failures in GMP -- all stability testing of batches of Gentocin "has revealed a contamination of the product" subsequently determined to result from a chemical leaching from the adhesive used to adhere the label to the product container. Despite determining the cause of the contamination, the FDA observed that:

> There is no evidence that the firm had taken any action to ensure the safety and efficacy of the Gentocin otic solution and has continued to distribute the product with the label causing ... the contamination. Furthermore, the firm has not determined the effect the leaching may have on other products, including Garamycin ophthalmic solution, which use labels with the same adhesive. (Emphasis added.)

83. The FDA conducted a follow-up inspection of the Kenilworth facility between November 11, 2000 and January 19, 2001. The FDA issued an eighteen page FDA 483 report on January 19, 2001 detailing continued widespread violations of GMP affecting multiple high profit products, including Claritin, Proventil, Nasonex, Vanceril, and Cancenase. The January 19, 2001 FDA 483 report starkly highlighted the Company's woefully deficient Quality Control function:

> The Quality Control Unit failed to assure that drug products were manufactured in compliance with cGMPs and therefore have the safety, quality, and purity that they purport, or are represented to possess. The Quality Control Unit failed to uphold their responsibilities to assure valid performance of manufacturing processes, suitability of equipment, support systems, and analytical methods for their intended use, and prevention of contamination through proper cleaning procedures. The process validation for many products fails to support claims that manufacturing processes were capable of consistently producing products with the same quality, purity, and safety.

84. In addition to multiple other deficiencies cited, the January 19, 2001 FDA 483 report found that even Clarinex -- Schering's purported new wonder drug destined to financially carry the Company into the future -- was not being manufactured in compliance with GMPs. The FDA specifically found:

> There was no assurance that the manufacturing process, parameters, equipment, or protocols and their acceptance criteria, conducted and generated at multiple sites for the production of Clarinex (Desloratadine Tablets, 5 mg.) are equivalent, or capable of producing product of the same quality.

85. Among the other adverse findings of the January 19, 2001 FDA 483 report were: (i) the Validation Department and Quality Control Unit routinely generate and approve protocols and reports which contain critical deficiencies; (ii) laboratory and manufacturing deviations were not adequately investigated according to written procedures, and in a way that provides a timely and scientific conclusion on which to base the disposition of a batch; and (iii) product quality review methods for the delivery of Albuterol through the actuator and particle size for Proventil Aerosol Inhaler were inadequate in that the methods exhibit various unidentified extraneous peaks. These adverse findings reflect the pervasive and continued failure of Defendants to adequately or reasonably manage the Company, despite years of hammering from the FDA.

86. In addition to the above FDA 483 report, on January 19, 2001 the Company also received an FDA "approvable letter" in connection with its pending new drug approval request for Clarinex. This letter notified Schering that the FDA would not approve the manufacture and marketing of Clarinex until Schering could demonstrate to the FDA's satisfaction that the long-standing GMP deviations had been resolved. The Company had disclosed that FDA final approval was the only factor delaying distribution of Clarinex before the spring 2001 allergy season, as the drug was otherwise ready for marketing to physicians and the public.

87. The seriousness of this development to Defendants and Schering cannot be overstated. As reported by Reuters on February 15, 2001, Clarinex is the "most important drug in the Company's pipeline because it is meant to be the successor to its top-selling medicine Claritin, which brings in $3 billion a year worldwide." The article further observed that "Schering-Plough had hoped to ship Clarinex to pharmacies for the coming [Spring 2000] allergy season that begins next month, in order to begin switching over Claritin users to Clarinex well before the older allergy drug's patent expires in December 2002." This switch-over is essential to the Company, as the enormous profits attributable to Claritin are expected to quickly evaporate when its patent expires. As the Reuters article notes, "[w]hen faced with generic competition, drugs typically lose up to 80 percent of their sales within one year--a threat spurring Schering-Plough to attempt to launch Clarinex as soon as possible and get people to use it."

88. It was not until February 15, 2001, that the Company finally publicly revealed Schering's projected reduced first quarter and full year 2001 earnings, and disclosed further delays in the rollout of both Clarinex and the Company's new asthma drug Asmanex, as the Company interrupted production in order to work to correct manufacturing problems previously cited by the FDA at its plants in New Jersey and Puerto Rico. Analysts projected a devastating six- to twelve-month delay in Clarinex approval.

89. On February 16, 2001, Schering sent the FDA a written response to the January 19, 2001 FDA 483 report. In a cover letter, defendant Cesan acknowledged the obvious, admitting to "the need to make broad, deep and lasting changes in our manufacturing and quality operations" and that "[o]ur basic approach to improving GMP compliance throughout the entire company must and will change." Not only were these admissions years too late, they also proved

to be empty rhetoric as repeated future FDA inspections in both New Jersey and Puerto Rico highlighted that Defendants continued to ignore their responsibilities to institute effective quality control and safe and effective manufacturing processes and practices at its key manufacturing facilities.

90. The FDA undertook yet another inspection of the Manati, Puerto Rico facility between February 1 and 16, 2000. Again, the FDA 483 report issued to Schering following the inspection highlighted multiple GMP violations affecting a wide array of the Company's prescription and over-the -counter drugs. Not the least of the GMP violations cited was a sweeping finding of pervasive quality control breakdown: "Your firm can not assure the processes used to manufacture finished pharmaceutical products can consistently produce product which meet their pre-determined specifications."

91. During this same two week period, the FDA also completed an inspection of the Las Piedras, Puerto Rico facility, resulting in the issuance of another adverse FDA 483 report, this one citing fourteen "inspectional observations" of GMP violations, including the almost identical sweeping quality control breakdown finding:

> Your validation process for several of your products reviewed is inadequate in that it fails to provide documented evidence that you are capable of producing a product with a high degree of assurance that the specific processes will consistently produce a product meeting it's predetermined specifications and quality attributes.

92. The FDA conducted yet another inspection at Las Piedras between May 1 and June 5, 2001. The resultant FDA 483 report again demonstrated the Company's continued

quality control abdication and the Defendants' failure and/or refusal to commit the time, attention, and resources necessary to effectively correct the Company's long-standing and pervasive manufacturing problems. Reflective of the Defendants' "do nothing" approach to Schering's manifest problems is one of the FDA's findings:

> Corrective action you committed to in your response dated October 12, 1999 to the FDA-483 issued on September 21, 1999 [almost two years previously] concerning data maintenance and security in laboratory instruments has not been completed ... . These systems have not been assessed and you have not developed the individual action plans necessary to bring these systems into compliance.

93. The FDA conducted another inspection of the Manati facility during the same period. This inspection, from May 1 through June 13, 2001, resulted in the issuance of a detailed, twenty-five page FDA 483 report of inspection. This FDA 483 report listed thirteen separate observations of GMP violations affecting virtually every product manufactured at the facility. The FDA's specific findings included:

> Your firm's Quality Assurance Unit lacks sufficient responsibility and authority to exercise the controls necessary to assure that consistent and reproducible manufacturing processes and controls are established and followed; that appropriate product specifications are established and followed; that scientifically sound and appropriate testing methods and procedures are established and followed; and that appropriate corrective actions are taken when process deviations or failures of product to meet established specifications occur for drug products manufactured by your firm.
>
> The Quality Assurance Unit also failed to assure that accurate and complete records of product and control activities were prepared and maintained appropriately and that timely, accurately and complete reports were submitted to the FDA when appropriate.

> Your firm does not have an adequate system for verifying the accuracy of production and control information to assure that oral and written information is consistent and correct. In addition, you do not have an adequate system to assure that relevant or required information is submitted to the FDA in a complete, accurate and timely manner.
>
> There is insufficient evidence to ensure that the current process used for manufacture of the [eight] products listed below will consistently produce a product meeting its predetermined specifications. In addition, none of the products cited during the previous inspection that ended on 2/16/01 for inadequate or lack of validation have been revalidated;
>
> You fail to have stability indicating analytical methods for the following products [with thirty-four products listed thereafter].

94. The FDA also conducted an additional inspection of the critical Kenilworth facility between May 7 and June 13, 2001. The adverse FDA 483 report the FDA issued for this inspection highlighted many of the same long-standing quality control and manufacturing problems, demonstrating the Defendants' continuing failure and/or refusal to commit the necessary resources and effort to institute even basic and fundamental corrections even at this critical facility, much less Company-wide. Specifically, the FDA found the following problems, all previously documented on the January 19, 2001 FDA 483 report, still remained uncorrected: (i) the lack of validation of the process used to manufacture Proventil Repetab; (ii) the inability of process validation studies to support current manufacturing processes; (iii) the lack of equipment qualification to assure proper performance of manufacturing and packing equipment; (iv) the lack of assurance that cleaning procedures were appropriate to prevent contamination of drug products; (v) the failure to address all unresolved deviations before approval [of HVAC

system] was obtained; and (vi) failure to complete work requests within specified timeframes to ensure proper functioning of equipment and control systems.

95. As detailed above, Defendants thus knew or recklessly disregarded at least twelve adverse FDA 483 reports of inspection and four stinging FDA Warning Letters received over a three year period targeting endemic and long-standing failures of quality control and manufacturing processes and practices at key manufacturing facilities affecting virtually all of the Company prescription and over-the-counter drugs, including its highest selling, most profitable products. Each successive FDA report resonated with the same theme, a virtual breakdown of basic and fundamental quality control and safe and compliant manufacturing practices, highlighting the Defendants' failure both to have insured the implementation of effective oversight and monitoring systems, and, even after this critical failure had repeatedly and starkly been brought to their attention, to still fail to take any effective action to rectify the problem. In the face of this barrage of high material adverse findings from the FDA, the Defendants instead chose to continue to subject the Company to unacceptable risk and exposure for economic and reputational injury and censure.

Insider Selling:

96. By the end of 2000, the Defendants knew or recklessly disregarded substantial adverse, non-public information about the Company's true financial condition and compliance with governmental regulations. As detailed above, this information included the devastating findings of the AAC report, the sweeping FDA condemnations in multiple FDA 483 reports and Warning Letters, and even the fact the FDA was at that time in the process of again inspecting the Kenilworth facility and even uncovering problems in the manufacturing and quality control of

Clarinex, with the reasonable likelihood of FDA approval for the drug being withheld -- as ultimately happened on January 19, 2001.

97. In the face of all this non-public, highly material adverse information, defendants Kogan, Cesan, Luciano, Mundy, and D'Andrade began to sell off large portions of their holdings of Schering stock. Specifically, Kogan sold 75,000 shares on December 15, 2000 for proceeds of $4.35 million, 105,769 shares on October 26, 2000 for proceeds of $5.6 million, 53,665 shares on June 26, 2000 for proceeds of $2.6 million and 75,000 shares on June 14, 2000 for proceeds of $3.65 million Defendant Cesan sold 44,500 shares on December 5, 2000 for proceeds of $2.4 million, and 25,057 shares on November 21, 2000 for proceeds of $1.3 million. Defendant D'Andrade sold 52,563 shares on October 9, 2000 for proceeds of $2.4 million, 66,309 shares on November 21, 2000 for proceeds of $3.5 million and 26,107 shares on December 6, 2000 for proceeds of $1.39 million. Defendant Luciano sold 65,264 shares on October 9, 2000 for proceeds of $3.1 million. Defendant Mundy sold 1,600 shares on December 29, 2000 for proceeds of $91,104.

DEFENDANTS' BREACH OF FUNDAMENTAL FIDUCIARY DUTIES

98. Defendants, as Schering's most senior executive officers, members of the Finance, Compliance and Audit Review Committee, and/or members of the Company's Board of Directors, violated their fiduciary duties by recklessly ignoring and failing to correct the long-term, persistent, prevalent, and recklessly deficient quality control standards and inadequate regulatory compliance procedures utilized in the Schering's manufacturing facilities for the Company's highest money-making products. Defendants, as the Company's senior-most management and directors, were also responsible for creating and helping to sustain the

dangerous corporate culture in which production and profitability were valued greater than quality, safety, and regulatory compliance. Defendants failed to provide adequate oversight, control, or resources to assure that the Company could effectively maintain the quality of its product and production facilities.

99. Defendants also acted in breach of their fiduciary duties of candor and due care by failing to fully disclose in the Company's SEC financial reporting the full extent and affect of the deficiencies in Schering's quality control and manufacturing processes and practices. Instead, Defendants concealed this material information in order to artificially inflate the price of Schering's stock and to maintain their positions with the Company. Schering and certain of its officers and directors have now been named as defendants in various federal securities law class actions, and the Company is subjected to millions of dollars of potential liability in connection with those securities law claims.

100. Certain of the Defendants have also wrongfully reaped huge personal profits by misappropriating the Company's material non-public inside information and, without disclosure thereof, selling substantial amounts of their Schering stock at market prices which were artificially inflated by reason of Defendants' failure to fully and adequately disclose material facts about Schering's business and financial condition.

101. In the last three months of 2000, and even just days prior to the Company's February 15, 2001 disclosure of reduced earnings expectations and delays on FDA approval of Clarinex , the following directors sold shares of Schering common stock for total proceeds of $37,993,449.88:

NAME	DATE OF SALE	AMOUNT	PRICE/SHARE	TOTAL PROCEEDS
Richard J. Kogan	06/14/00	75,000	$48.66	$3,650,000.00
	06/26/00	53,665	$48.45	$2,600,000.00
	10/26/00	20,100	$52.88	$ 1,062,888.00
	10/26/00	83,400	$52.93-$53.31	$ 4,422,550.00
	10/26/00	2,269	$53.38-$53.44	$ 121,153.00
	10/26/00	40,231	$53.50	$ 2,152,358.50
	12/01/00	56,669	$53.63	$ 3,039,158.47
	12/15/00	75,000	$58.00	$ 4,350,000.00
	02/06/01	11,964	$40.06	$ 479,277.84
TOTAL:		**418,298**		**$21,877,385.81**
Carl E. Mundy	12/29/00	**1,600**	$56.94	**$ 91,104.00**
Hugh A. Dandrade	10/09/00	52,563	$46.13-$46.38	$ 2,426,304.00
	11/21/00	66,309	$53.50	$ 3,547,532.50
	11/21/00	18,891	$52.00	$ 982,332.00
	12/01/00	14,573	$53.63	$ 781,549.99
	12/06/00	26,107	$53.38-$53.56	$ 1,394,061.00
TOTAL:		**178,443**		**$ 9,131,779.49**
Raul E. Cesan	11/21/00	25,057	$53.94	$ 1,351,574.58
	12/05/00	44,500	$54.50	$ 2,425,250.00
TOTAL:		**69,557**		**$ 3,776,824.58**
Robert P. Luciano	10/09/00	**65,264**	$47.75	**$ 3,116,356.00**
GRAND TOTAL:		**733,162**		**$37,993,449.88**

102. Defendants also intentionally or recklessly authorized and/or permitted the Company to engage in improper sales practices which operated as a fraud upon federal and state governmental authorities, thereby exposing the Company to a series of ongoing federal and state investigations and jeopardizing its all-important eligibility to participate in Medicaid and other government programs.

103. At least by late 1999, Defendants were confronted with evidence that the Company was engaging in illegal sales practices and, as a result, was exposed to substantial criminal and/or civil liability. In late 1999, the Company received a subpoena from federal prosecutors in Philadelphia, who were investigating its sales practices with respect to the Company's flagship Claritin product.

104. By September 2000 at the latest, Defendants had received additional evidence that the Company was breaking the law. In that month, Texas Attorney General John Cornyn sued the Company's Warrick Pharmaceuticals unit, alleging that Warrick had overcharged the state's Medicaid program by falsely inflating the prices it reported for the generic asthma drug Albuterol.

105. Defendants continued to receive further warnings that the Company was illegally overbilling state and federal governments in connection with their Medicaid programs. On March 14, 2001, the Company disclosed that the United States Department of Justice, the U.S. Department of Health and Human Services, the U.S. Attorney's Office in Boston, and state government authorities were investigating its drug marketing practices as part of a criminal probe of the pharmaceutical industry. According to the Company, authorities were investigating whether it caused "unlawful inflation" of government reimbursements for certain drugs, which the Company did not identify, by misrepresenting to the government the average wholesale price of the drugs, upon which price government reimbursements are based.

106. The Company further disclosed that state and federal authorities are investigating whether it shorted Medicaid on payments aimed to ensure the government pays the lowest price for drugs. One issue is whether the Company, in violation of law requiring manufacturers to

report "best prices" for drugs, employed a practice known as "repackaging" whereby it secretly reduced required payments to state and federal Medicaid programs by not disclosing steep discounts on bulk sales of drugs which are then repackaged for sale to physicians.

107. In the face of these repeated warnings, Defendants intentionally or recklessly refused to take appropriate action to investigate and/or halt these illegal practices, and in fact intentionally and/or recklessly authorized and/or permitted the continuation of these practices, despite the unmistakable potential for severe adverse economic and reputational injury to the Company.

DERIVATIVE ALLEGATIONS

108. Plaintiffs bring this action derivatively in the right and for the benefit of Schering to redress injuries suffered and continuing to be suffered by Schering as a direct result of the breaches of fiduciary duty and violations of laws alleged herein. Plaintiffs will adequately and fairly represent the interests of Schering in enforcing and prosecuting its rights.

A. Demand Futility Allegations

109. Plaintiffs have not made any demand on the Board to institute this action. Demand is excused here because it would be a futile and useless act.

110. A majority of Schering's current board, as senior most executives, members of the Finance, Compliance and Audit Review Committee of the Board of Directors, and/or directors of long-standing, were directly responsible for both the failure to implement and maintain adequate and reasonable systems to ensure even minimally acceptable standards of quality control and safe and regulatorily compliant drug manufacture, and for the failure and/or refusal to take adequate

and reasonable steps to correct this critical defect even when faced with multiple clear and unambiguous red flags from the FDA, in-house personnel, and paid outside consultants.

111. Specifically, Defendants had access to and a duty to know about such highly significant adverse facts as:

(i) that the FDA conducted at least a dozen inspections of principal manufacturing facilities in New Jersey and Puerto Rico, resulting in the issuance of multiple, highly adverse inspection reports and even four FDA Warning Letters over the course of several years;

(ii) that these adverse FDA inspection results and Warning Letters repeatedly highlighted the gross lack of any adequate quality control function or systems at these facilities;

(iii) that these adverse FDA inspection results and Warning Letters raised significant concerns about the manufacturing processes of virtually every prescription and over-the-counter pharmaceutical product the Company manufactured at these facilities, including the hugely profitable products Claritin and asthma aerosol inhalers, and even the Company's future "wonder drug" Clarinex;

(iv) that the problems reflected in these adverse inspection reports and Warning Letters forced the Company to instigate at least three product recalls, entailing millions of units of several products, at huge economic and reputational costs to Schering, and put at risk the ultimate FDA approval to manufacture and market Clarinex;

(v) that the Company had undertaken at least two separate audit inspections of the critical Kenilworth facility, the first with in-house personnel and the second with outside paid

consultants, and that the confidential report by the outside consultant offered a blistering indictment against the Company's lax manufacturing practices, unhealthy morale, gross lack of management guidance, and virtual absence of any meaningful quality control program; and

(vi) that over the entire period, the Company had undertaken little or no real effort to confront these issues or rectify the substantial problems they posed for Schering.

112. Defendants Becherer, Morley, Herzlinger, Osborne, van Oordt, and Weinbach were members of the Finance, Compliance and Audit Review Committee of the Board of Directors. The Finance, Compliance and Audit Review Committee Charter sets forth the duties and responsibilities of the members of this important committee, which include assisting the Board in its oversight function by monitoring the Company's financial reporting process and compliance with legal and regulatory requirements.

113. According to the Committee Charter, Committee members' responsibilities for the financial reporting process include: "review[ing] with outside auditors the report of their annual audit, or proposed report of annual audit, the accompanying management letter, if any, and the reports of their reviews of the Company's interim financial statements."

114. Likewise, Committee members' responsibilities for the compliance process include: "review[ing] the Corporation's program to monitor compliance with the Corporation's Business Conduct Policy, laws and regulations, and meet[ing] periodically with the Corporation's management and General Counsel to discuss compliance."

115. Defendants Becherer, Morley, van Oordt, and Osborne have been members of this Committee since at least 1997, and defendants Herzlinger and Weinbach joined the Committee

in 2000. These defendants thus had a heightened responsibility for overseeing the Company's internal audit function, business conduct policy, and compliance with laws and regulations. As such, these defendants were directly responsible for failing to assure that Schering had in place adequate systems to timely identify and correct quality control and manufacturing deficiencies that violated, inter alia, regulatory imposed GMPs.

116. In addition, defendants Luciano (a director since 1978), Herzlinger (a director since 1992), Mundy and Russo (directors since 1995), and Wood and Miller (directors since 1997), as long-standing directors of Schering, knew or were reckless in not knowing the critical, material adverse facts set forth above at ¶111, and are thus also directly liable for breaching their duty of care by failing to take adequate and reasonable steps in light of this adverse information to implement and monitor Schering's deficient quality control and manufacturing regulatory compliance. Instead, the Defendants acted with knowledge or reckless disregard in allowing the Company to continue to operate key manufacturing facilities in a manner that blatantly failed to satisfy basic quality, safety, and sanitary regulations and/or standards.

117. In addition, defendants Kogan, Cesan, D'Andrade, Luciano, and Mundy are liable for breaching their duty of loyalty by trading in Schering stock based on highly material, non-public information.

118. The Board, at the time of the filing of plaintiffs' Complaint, is made up entirely of persons who are alleged herein as principal wrongdoers having acted with actual knowledge or reckless disregard of wrongdoing. The Directors all were personally and directly involved in the acts of mismanagement and/or disloyalty alleged herein. Consequently, the entirety of Schering's Board has direct and personal financial interests in the outcome of the litigation and

the alleged wrongdoing that prevent any of the Defendants from exercising an unbiased business judgment as to whether to proceed with this action. In order to bring this action, Defendants would have been required to sue not only themselves but also their fellow directors and allies in the top ranks of the Company with whom they have long-standing and interlocking personal and business relationships, and with whom they have entangling financial alliances, interests, and dependencies.

119. The acts complained of herein constitute violations of law, breaches of the fiduciary duties owned by Defendants, and waste of corporate assets. Such acts are legally incapable of ratification.

120. At all relevant times, the Board operated as a collective entity through periodic meetings held either in person or telephonically where they discussed matters affecting the Company's business and reached collective and consensual decisions regarding actions taken. The Board members were either fully informed of the facts alleged herein, or were reckless in failure to be so informed, and could not have reasonably believed that their conduct was in conformity with GMPs or other applicable regulations. With respect to the breaches of loyalty resulting from trading on inside information, the selling defendants did not act with the best interest of the Company in mind. Rather, they subjected the Company to attack and sought to reap personal financial gain by trading on non-public inside information. As a result, the acts which Defendants both explicitly and tacitly approved cannot be the product of a valid business judgment.

121. Thus, as alleged herein, demand is excused because this Derivative Complaint alleges with particularity that a majority of the Company's directors intentionally or recklessly

either: (i) sold substantial amounts of Schering stock at prices artificially inflated by false and misleading public statements regarding the true condition of the Company: (ii) ignored repeated specific warnings from federal regulators and others that Schering's quality control systems and manufacturing processes were inadequate and not in compliance with applicable federal regulations; (iii) that the Company was engaging in systematic illegal sales practices; and (iv) in the face of these warnings, decided not to adopt reasonable internal controls and independent monitoring systems over Schering's manufacturing processes and sales practices.

122. Defendants' conduct described in this Complaint could not have been the product of legitimate business judgments as it was based on intentional, reckless and/or self-interested misconduct. Thus, none of the Defendants, who constitute a majority of the boards of directors of the Company, can claim exculpation from their violations of duty pursuant to the Company's charter. As a majority of the directors on the Board of Directors of Schering face a substantial likelihood of liability, they cannot be presumed to be capable of exercising independent and disinterested judgment about whether to pursue this action on behalf of the Company. Accordingly, demand is excused as being futile.

B. Demand Allegations

123. On December 21, 2001, Schering announced that it was in negotiations with the FDA for a consent decree to resolve issues involving the Company's manufacturing problems which included payment of $500 million arising out of those violations. On December 26, 2001, Plaintiff Scherr sent a demand letter (the "Demand Letter") to the Company's Board demanding, among other things, that the Company take legal action against certain top executives based on the above alleged manufacturing problems and resulting injury to the Company. Counsel for

Scherr met with counsel for the Company in connection with the concerns raised in the Demand Letter.

124. The Board created an Evaluation Committee in January 2002 to consider, *inter alia*, the claims raised in the Demand Letter related to manufacturing issues at Schering's facilities and the FDA's decision to delay the approval of Clarinex. In October 2002, Dr. Scherr's counsel met with counsel for Schering and communicated with the Evaluation Committee and its counsel.

125. In November 2002, counsel for the Evaluation Committee notified Scherr's counsel that the Evaluation Committee had recommended, and the Board concurred that, *inter alia*, the Company refuse Scherr's demand.

126. Scherr alleges that this refusal of his demand is improper and unreasonable.

COUNT I
Against All Defendants for
Breach of Fiduciary Duty

127. Plaintiffs incorporate by reference each of the foregoing allegations.

128. Defendants owed to Schering the highest duties of loyalty, honesty, diligence, and fairness in conducting the Company's affairs in a lawful manner.

129. At a minimum, to discharge these duties, each defendant should have exercised reasonable and prudent supervision over the management, policies, practices, controls and financial affairs of the Company. By virtue of these obligations, each defendant was required, inter alia:

(i) to exercise reasonable control and supervision over the officers, employees, agents, business, and operations of the Company;

(ii) to be and remain informed as to how the Company was operating and, upon receiving notice or information of an imprudent, questionable condition, or practice, make reasonable inquiry and, if necessary, make all reasonable remedial efforts; and

(iii) to conduct the affairs of the Company to provide the highest quality services and maximize the profitability of the Company for the benefit of its shareholders.

130. As described herein, Defendants knowingly or with recklessness breached their fiduciary duties by orchestrating, devising, carrying out, participating in, and/or failing to prevent, terminate, or timely correct the wrongdoing alleged herein, which included:

(i) directing the business and operations of Schering in such a manner as to put production before quality and regulatory compliance;

(ii) failing to assure that adequate resources, systems, policies, and procedures were in place to ensure that Schering's manufacturing facilities operated in compliance with GMPs and other FDA regulations;

(iii) failing to respond in a timely and effective manner to the repeated adverse FDA inspection reports and Warning Letters and the highly critical AAC report;

(iv) allowing directors and senior officers of Schering to trade in the Company's stock while in possession of material non-public information; and

(v) making false and misleading statements to the public and/or concealing material and adverse information, subjecting the Company to liability for violation of the federal securities law.

131. Each of these violations was achieved because Defendants willingly, knowingly, and/or with recklessness allowed Schering to continue, despite multiple, explicit, and clear

warnings from the FDA, to operate without adequate policies or procedures in place to assure reasonable quality control, and that violations of federal regulations or guidelines were not made in the manufacture of the Company's pharmaceutical products. Any purported warnings issued by the Company or any defendant that generally discussed the risks faced by Schering as a result of the manufacturing facilities' deficiencies were not sufficient, and concealed from the public that Schering failed to follow acceptable policies and procedures for maintaining production quality and compliance with applicable regulatory standards.

132. As a direct and proximate result of the Defendants' violations of their fiduciary duties, Schering has been injured. Schering's reputation for conducting and/or supporting effective, accurate and ethical manufacture of pharmaceutical products has been permanently tarnished. Schering's development and marketing of Clarinex has been put at substantial risk and has been postponed because the FDA will not grant approval to the drug until the GMP deficiencies at the Company's manufacturing facilities are resolved. Schering has been forced to recall products and to shut down a number of its production lines in order to undertake drastic changes to insure compliance with the GMPs and other regulatory standards. Schering has been named as a defendant in numerous federal securities law class action lawsuits as a direct result of their failure to fully disclose to the public the depths of Schering's GMP deficiencies. Schering has been injured to the extent it has already had to respond to these suits, and will continue to incur the expense of litigation as well as the risk of judgment because of Defendants' wrongful conduct alleged herein. The exact amount of Schering's total damages are not presently determinable.

133. Plaintiffs also seek to recover from defendants Kogan, Cesan, Luciano, Mundy, and D'Andrade for their breaches of their duty of loyalty by usurping non-public corporate information for their own personal gain. Under applicable law, these defendants must disgorge their ill-gotten gains in illegal trading in Schering stock. To date, neither Defendants nor the Company have made any effort to recoup, on the Company's behalf, the illegal profits obtained by these defendants' insider trading. The Company is entitled to recover these improperly obtained profits regardless of whether the Company suffered any damages. Accordingly, plaintiffs, as shareholders of the Company, seeks, on behalf of Schering, monetary damages, injunctive remedies, and other forms of equitable relief.

134. Plaintiffs further bring this action as current shareholders of Schering on behalf of Schering to obtain indemnification for all damages suffered by Schering and a judicial determination that each of the Defendants is obligated to indemnify and hold Schering harmless from any and all such damages, judgments or other awards, including attorneys' and expert fees, that may be recovered against Schering in any litigation relating to the Defendants' breaches of duty, including the federal securities law class actions. Further, plaintiffs, on behalf of Schering, seek recovery of all damages suffered by Schering as a result of Defendants' breaches of duty.

135. Plaintiffs also seek: (1) the creation of a committee of board members to constitute a separate compliance committee consisting solely of independent board members with the authority to engage independent outside consultants and other professionals to carry out the mandate of the committee to devise and implement quality control and compliance initiatives; (2) the creation of operating units at the corporate level reporting directly to Schering's board to investigate and address "good manufacturing practices" and devise and implement uniform

procedures to be used throughout the company for compliance with all applicable FDA requirements; (3) the creation of a corporate department reporting directly to Schering's board to be the company's liaison with the FDA on all manufacturing issues; (4) the imposition of corporate practices and procedures which require any internal quality control or compliance task forces to report directly to a committee of independent directors of Schering's board.

WHEREFORE, plaintiffs demand judgment as follows:

A. Declaring that the Defendants, and each of them, have breached their fiduciary duties as alleged herein;

B. Directing Defendants, jointly and severally, to account for all losses and/or damages sustained by the Company by reason of the acts and omissions complained of herein;

C. Requiring Defendants to remit to the Company all of their salaries and other compensation received for the periods when they breached their duties;

D. Awarding compensatory damages or money damages against all Defendants, jointly and severally, in favor of Schering for all losses and damages suffered as a result of the acts and transactions complained of herein;

E. Declaring that the Defendants are obligated to indemnify and hold Schering harmless from any fines, penalties, judgment, settlement or award pursuant to any of the class actions pending or to be filed against Schering or its employees or agents arising out of the breaches of duty and wrongdoing alleged herein;

F. Declaring that each of the insider trading defendants be compelled to disgorge the proceeds of his trading based on inside information and that the Company recover such proceeds to prevent these defendants from being unjustly enriched by their breach of duty;

G. Directing that all Defendants account for all damages caused by them as a result of their unlawful conduct;

H. Ordering that Defendants and those under their supervision and control refrain from further violations as are alleged herein and to implement corrective measures, including a system of internal controls and procedures sufficient to prevent the repetition of the acts complained of herein, that will rectify all such wrongs as have been committed and prevent their recurrence;

I. Awarding pre-judgment and post-judgment interest as allowed by law;

J. Awarding plaintiffs their costs and expenses for this action, including reasonable attorneys' and experts' fees; and

K. Granting such other and further relief as this Court may deem just and proper.

Dated: May 25, 2007

SQUITIERI & FEARON, LLP

By: _____
OLIMPIO LEE SQUITIERI (LS-1684)

2600 Kennedy Boulevard
Jersey City, NJ 07306
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Fax: (201) 200-9008

VERIFICATION

I, Philip E. McCarthy, hereby verify under penalties of perjury that: (1) I am a shareholder of Schering-Plough Corporation ("Schering") and have been so continuously at all times relevant to this action; and (2) the remaining facts set forth in the foregoing Joint and Consolidated Second Amended Shareholder Derivative Complaint are true and correct to the best of my knowledge, information and belief.

Date: May 19th, 2007

PHILIP E. McCARTHY

VERIFICATION

I, William W. Prager, Jr., hereby verify under penalties of perjury that: (1) I am a shareholder of Schering-Plough Corporation ("Schering") and have been so continuously at all times relevant to this action; and (2) the remaining facts set forth in the foregoing Joint and Consolidated Second Amended Shareholder Derivative Complaint are true and correct to the best of my knowledge, information and belief.

Date: May 21, 2007

WILLIAM W. PRAGER, JR.

I verify the above signature of William W. Prager, Jr.

5/21/07

VERIFICATION

I, David Sherr, hereby verify under penalties of perjury that: (1) I am a shareholder of Schering-Plough Corporation ("Schering") and have been so continuously since before the time my counsel sent a demand letter to the board of directors of Schering in December 2001; and (2) the remaining facts set forth in the foregoing Joint and Consolidated Second Amended Shareholder Derivative Complaint are true and correct to the best of my knowledge, information and belief.

Date: May 29, 2007

David Sherr